Testimony
Before the Committee on Government Reform
United States House of Representatives

The Science of Reduced Risk Tobacco Products

Statement of

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Good afternoon. I am Dr. Scott Leischow, Chief of the Tobacco Control Research Branch at the National Cancer Institute (NCI), of the National Institutes of Health. Thank you, Representative Davis and distinguished Members of the Committee for the opportunity to be with you today to discuss the issue of tobacco "harm reduction." Let me begin by emphasizing three fundamental facts: (1) all tobacco products are hazardous, (2) there is no safe level of tobacco use, and (3) the only proven way to reduce the enormous burden of disease and death due to tobacco use is to prevent its use and to help users quit.

In NCI's view, a product would be "harm reducing" if it actually reduces disease and death for both individuals and the population as a whole. This is an important distinction because even if a tobacco product is shown to reduce disease risk in an individual, the availability of products that claim reduced harm may have harmful consequences on the population. For example, smokers may see reduced harm products as a viable alternative to quitting. Similarly, there is the risk that smokers who have quit will return to using tobacco because they think that these products make it safe to do so.

The National Institutes of Health has funded many studies on the health effects of tobacco over the past 50 years, and is currently funding a small number of

investigator-initiated grants on tobacco product health effects. We have also added questions about tobacco product use and perceptions of tobacco products' health risk to NCI's Health Information National Trends Survey. Additionally, the Centers for Disease Control and Prevention laboratory is analyzing the chemistry of some newer tobacco products. The tobacco industry also funds research on "harm reducing" tobacco products. However, we know very little about their studies, and it is uncertain how many have been made available for objective scientific scrutiny. A broad-based research effort involving numerous scientific disciplines is needed to answer critical questions about potential tobacco harm reduction products. The IOM Report entitled "Clearing the Smoke," and the conclusions of the 2001 Reducing Tobacco Harm conference that were published by Hatsukami and others, recommend key research questions to be addressed.

We also need to be mindful of the lessons we learned from our experience with so-called "low tar and low nicotine" cigarettes. When the causal relationship between cigarette smoking and lung cancer was first established in the 1950s, the tobacco industry began altering its products by first adding filters to cigarettes, and in the 1960s began marketing so-called "low tar and low nicotine" cigarettes. However, because an extensive objective testing program of those products was not put into place, it took more than 20 years to conclude

that smokers who switched to light cigarettes did not reduce their lung cancer risk. Research summarized in a recent NCI Monograph[1] shows that many smokers switch to lower yield cigarettes out of concern for their health in the belief that these cigarettes are less risky or are a step toward quitting. In fact, the Monograph concluded that marketing and promotion of reduced yield cigarettes may delay genuine attempts to quit. The light cigarette experience taught us valuable lessons that we should not repeat in the future.

There are 46 million adult smokers in the U.S., which represents just over 23% of the population. The prevalence of smoking has decreased considerably since the early 1960s, and during the 1990s prevalence dropped approximately 1% per year. Today, we have much to offer people who smoke and want to quit, including effective behavioral treatments and medications. Smoking cessation medications must undergo extensive testing for safety and effectiveness, and be scrutinized through objective review, prior to their release to the public. When used as directed, about 25% of those using such products are able to quit smoking. There is no clinical evidence that long-term use of nicotine replacement medications causes harm.

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[1] David Burns, M.D. and Neal L. Benowitz, M.D., *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine,* Smoking and Tobacco Control Monograph Series vol. 13, 2001.

Unlike nicotine replacement products for smoking cessation, tobacco products do not undergo rigorous objective scrutiny either for their product constituents or tobacco industry claims. Tobacco contains many disease-causing substances, including tobacco-specific nitrosamines, formaldehyde, arsenic, and benzopyrene, and restrictions on marketing are few. Thus, a new tobacco product - marketed for harm reduction might sit on a store's shelf next to an FDA-approved nicotine replacement product which is marketed for smoking cessation. It is possible that the similarity of these products will be confusing to the public, and imply that a tobacco product is safe and FDA-approved when it is not.

The NCI developed a position in 1991 where we recommended that the public avoid and discontinue the use of all tobacco products, including smokeless tobacco. Additionally, the NCI stated that nitrosamines, found in tobacco products, are not safe at any level. Because the accumulated scientific evidence does not support a change, we continue to endorse these statements. Furthermore, we do not have enough evidence to conclude that smokeless tobacco is a less hazardous alternative to cigarettes.

A framework needs to be developed and implemented for the independent

and objective scientific collection, review and interpretation of data on tobacco products purported to reduce harm. This approach is vitally important so that data are optimally synthesized and disseminated to scientists, health providers, policymakers, and the public. This will ensure that the public has accurate, unbiased information on risk and harm prior to being faced with deciding whether to use one of these tobacco products, an FDA-approved medication, or no product at all.

The evaluation of new tobacco products purported to reduce harm needs to be part of a broad tobacco control and prevention initiative. We know that smokeless tobacco use causes disease. We do not know whether there may be any potential benefit in promoting to current smokers the use of any products purported to reduce harm. The only proven way to reduce the death and disease caused by tobacco use is to prevent youth from starting to smoke, and to help current smokers to quit. These are and must remain our highest priorities.

Thank you again for this opportunity to provide comments regarding this significant public health issue. I am happy to answer any questions you may have.